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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/799,163	03/12/2004	John W. Holaday	05213-0077 (43170-296614)	8159

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EXAMINER	
YAEN, CHRISTOPHER H	

ART UNIT	PAPER NUMBER
1643	

DATE MAILED: 07/12/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/799,163	HOLADAY ET AL.	
	Examiner	Art Unit	
	Christopher H. Yaen	1643	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *24 April 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-11* is/are pending in the application.

4a) Of the above claim(s) *1 and 2* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *3-11* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *12 March 2004* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *8/16/2004*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☒ Other: *exhibit 1*.

DETAILED ACTION

Re: HOLADAY ET AL

Election/Restrictions

1. Applicant's election with traverse of Group II (claims 3-4) in the reply filed on 4/24/2006 is acknowledged. The traversal is on the ground(s) that the restriction requirement is improper. Specifically, Applicant indicates that the search for the group I would necessarily include the invention of group II. Therefore there would be little burden to search both groups. Applicant's arguments have been carefully considered but are not found persuasive because the inventions of groups I and II have been classified in different classes and subclasses. Moreover, prior art that may apply to the product may not necessarily apply to a method of using said product in that particular method or in any method. Finally, the search for the product and the method is neither co-extensive and nor overlapping and such a search would be considered burdensome given the reasoning set forth in the last office action (see action mailed 3/24/2006).

The requirement is still deemed proper and is therefore made FINAL.

2. Claims 1-11 are pending and claims 5-11 are newly added.

3. Claims 1-2 are withdrawn from further consideration as being drawn to non-elected inventions.

4. Claims 3-11 are examined on the merits.

Information Disclosure Statement

5. The Information Disclosure Statement filed 8/16/2004 is acknowledged and considered. A signed copy of the IDS is attached hereto.

Priority

6. The instant application claims priority to numerous CIP applications (i.e. 09/266,543 (now US Patent 6,805,865) filed 3/11/1999; 09/265,213, filed 3/10/1999; and 08/467,101, now US Patent 5,919,459) and continuations of the CIP (80/271,557, filed 7/7/1994; and 08/068,717, filed 5/27/1993). None of the priority documents support the specific claim limitation of the instant invention. For example, the instant invention is drawn to a composition comprising a peptide of SEQ ID No: 10. Support for these claim limitations cannot be found in any of the earlier filed applications because none of the earlier filed applications recite or teach SEQ ID No: 10. Therefore, the filing date of the instant application (i.e. 3/12/2004) will be used for the determination of prior art. Applicant is invited to point to specific support (i.e. page and line number of the application) for the instantly claimed inventions.

Claim Rejections - 35 USC § 112, 1st paragraph

7. Claims 3-11 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a composition comprising a growth factor composition comprising SEQ ID No: 10 for reducing cancer, does not reasonably provide enablement for a vaccine composition comprising a growth factor comprising SEQ ID No: 10 for "preventing" cancer. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

Factors to be considered in determining whether a disclosure meets the enablement requirement of 35 USC 112, first paragraph, have been described by the court in *In re Wands*, 8 USPQ2d 1400 (CA FC 1988). Wands states at page 1404,

> "Factors to be considered in determining whether a disclosure would require undue experimentation have been summarized by the board in Ex parte Forman. They include (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims."

The nature of the invention

The claims are drawn to a composition comprising an effective amount of a growth factor vaccine composition comprising SEQ ID No: 10. The invention is in a class of invention which the CAFC has characterized as "the unpredictable arts such as chemistry and biology." *Mycogen Plant Sci., Inc. v. Monsanto Co.*, 243 F.3d 1316, 1330 (Fed. Cir. 2001).

The breadth of the claims

The claims encompass vaccines which are a capable of preventing cancer.

The unpredictability of the art and the state of the prior art

Stedman's medical dictionary has defined a vaccine as a "preparation intended for active immunological prophylaxis" (see Exhibit 1). The treatment of cancer is at most unpredictable as underscored by Gura (Science, v278, 1997, pp.1041-1042) who discusses the potential shortcomings of potential anti-cancer agents including extrapolating from in-vitro to in-vivo protocols, the problems of drug testing in knockout mice, and problems associated with clonogenic assays. Indeed, since formal

screening began in 1955, thousands of drugs have shown activity in either cell or animal models, but only 39 that are used exclusively for chemotherapy, as opposed to supportive care, have won approval from the FDA (page 1041, 1st column) wherein the fundamental problem in drug discovery for cancer is that the model systems are not predictive. Further, Bellone *et al.* . (Immunology Today, v20 (10), 1999, pp.457-461) summarize the current state of the art of peptide immunotherapy including clinical trials where "there is usually a poor correlation between induction of specific T-cells and the clinical responses" (page 457, 2nd column). Bellone *et al* teach the disadvantages of peptide cancer immunotherapy in that (1) there is no direct evidence for a role in tumor rejection, (2) the therapy is applicable to few patients, (3) risk of generating tumor escape mutants, and (4) risk of autoimmune reactions (page 461, Box 1). All of this underscores the criticality of providing working examples for a composition that prevents cancer, all of which is not disclosed in the specification, particularly in an unpredictable art, such as cancer therapy.

Working examples

The speciation of the instant application teaches that a composition comprising the peptide of SEQ ID No: 10 is capable of producing both a humoral and a cellular immune response (see page 34, for example). The working examples teach that the administration of a composition comprising SEQ ID No: 10 was able to induce a memory response in an animal model.

Guidance in the specification

The specification provides insufficient guidance and objective evidence that such a composition is capable of providing a prophylactic response implied by the term "vaccine." The specification provides no guidance on the administration of the claimed composition or any portion thereof in vivo that is encompassed by the claimed product. No information regarding the protective or prophylactic effects or ability of the claimed vaccine composition to "prevent" cancer or any diseases associated with angiogenesis has been provided in the specification as originally filed.

Level of skill in the art

The level of skill in the art is deemed to be high.

Conclusion

Thus given the broad claims in an art whose nature is identified as unpredictable, the unpredictability of that ad, the large quantity of research required to define these unpredictable variables, the lack of guidance provided in the specification, the presence of a working example which does not address the issue of the efficacy of the control and the negative teachings in the prior art balanced only against the high skill level in the art, it is the position of the examiner that it would require undue experimentation for one of skill in the art to perform the method of the claim as broadly written.

Claim Rejections - 35 USC § 102

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

9. Claims 3-11 are rejected under 35 U.S.C. 102(b) as being anticipated by Holaday *et al* (WO 00/53219). Holaday *et al* teach a composition comprising a peptide of SEQ ID No: 10 (see page 28, for example) and further teach that the composition is formulated with pharmaceutically acceptable carriers such as liposomes, vesicles, colloidal gold (see page 8, for example), and carrier proteins (see page 21, for example) wherein the carrier proteins comprise those listed in claims 7 (see page 21, for example). Holaday *et al* further teach that the composition further comprises adjuvants, preservatives, diluents, emulsifiers, or stabilizers, wherein the adjuvants are those disclosed in claim 9 (see page 21, for example). Holaday *et al* also teach hyperproliferative disorders (see page 30, for example).

Therefore the claims are anticipated by the prior art.

Conclusion

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christopher H. Yaen whose telephone number is 571-272-0838. The examiner can normally be reached on Monday-Friday 9-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Helms, Ph.D. can be reached on 571-272-0832. The fax phone

number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Christopher Yaen
Art Unit 1643
June 27, 2006

CHRISTOPHER H. YAEN
PRIMARY EXAMINER

Exhibit 1

Stedman's Medical Dictionary 27th Edition

vaccine (vak'sen, vak-sen')

Originally, the live *v.* (vaccinia, cowpox) virus inoculated in the skin as prophylaxis against smallpox and obtained from the skin of calves inoculated with seed virus. Usage has extended the meaning to include essentially any preparation intended for active immunologic prophylaxis; e.g., preparations of killed microbes of virulent strains or living microbes of attenuated (variant or mutant) strains; or microbial, fungal, plant, protozoal, or metazoan derivatives or products. Method of administration varies according to the *v.*, inoculation being the most common, but ingestion is preferred in some instances and nasal spray is used occasionally. SYN: vaccinum. [L. *vaccinus*, 1 relating to a cow]